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| EXAMINER | |
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| CARTER, KENDRA D | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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| ***Office Action Summary*** | **Application No.**<br>10/685,974 | **Applicant(s)**<br>DEECHER ET AL. |
| | **Examiner**<br>KENDRA D. CARTER | **Art Unit**<br>1617 |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1and 14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2009 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of December 9, 2008 made to the office action filed October 7, 2008. Claims 1 and 14-22 are pending. Claims 1, 14, 21 and 22 are amended and claims 2-13 and 23-24 are cancelled.

In light of the claim amendments, all of the following 35 USC 103(a) rejections are withdrawn: 1) rejection of claims 1, 4, 14-18, 21 and 22 being unpatentable over Berendsen, in view of Stearns et al. and Janowsky et al.; and 2) claims 5 and 6 as being unpatentable over Berendsen in view of Stearns et al., Janowsky et al. and Carr et al.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 USC 103(a) rejection of claims 19 and 20 as being unpatentable over Berendsen in view of Stearns et al., Stearns et al., Janowsky et al, and Quella et al. were found not persuasive, thus the rejection is maintained.

Due to the new amendment to the claims and further consideration, the new and modified 35 U.S.C. 103(a) and 112, first paragraph rejections are made below. Applicant's arguments have been addressed below.

### *Claim Rejections - 35 USC § 112*

**1) Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hot flush, does not reasonably provide enablement for the prevention or cure of hot flush. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.**

The instant claims are drawn to a method of treating hot flush in a subject comprising administering desipramine and is (+)-a- (2,3-dimethoxyphenyl)-l\- [2-(4-flurophenyl)ethyl]-4-piperidinemethanol (MDL-100907). The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 1 is drawn to "a method for treating hot flush in a subject, comprising the step of: administering to said subject an effective amount of desipramine, its derivatives and or pharmaceutically acceptable salts thereof in combination with an effective amount of is (+)-a- (2,3-dimethoxyphenyl)-l\- [2-(4-flurophenyl)ethyl]-4-piperidinemethanol its derivatives and or pharmaceutically acceptable salts thereof."

(2) The breadth of the claims:

Claim 1 embraces and reads of preventing and curing hot flush. The specification does not enable the prevention or the cure of hot flush.

(3) The state of the prior art:

The state of the art regarding preventing or curing hot flush is very low or do not exist. Barton et al. (Support Cancer Ther., Sep 2007, vol. 4, No. 4, pp. 219-224) teach that desipramine did not reduce hot flashes beyond the 25%-30% reduction that would be expected with placebo (see abstract, last 5 lines). Berendsen teaches that it is believed that the 5-HT2a receptor subtype may play a key role in the occurrence of hot flushes (see abstract, in particular.) In particular, Berendsen teaches that blockade of 5-HT2a receptors by treatment with the 5-HT2 receptor blocker mirtazapine reduced the frequency and intensity of hot flushes (see pages 159-160, Section 1, in particular.) Since MDL-100907 is a 5-HT2a agonist, one would expect it to be effective in reducing the frequency and intensity of hot flushes. Therefore, neither compound prevents or cures hot flush.

(4) The predictability or unpredictability of the art:

The predictability of preventing or curing hot flush is relatively low. Therefore, to one skilled in the art, preventing or curing hot flush is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high as demonstrated by Barton et al.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the preventing or curing hot flush is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that prevent or cure hot flush. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02. The current specification defines treating or treatment to include preventative, prophylactic, curative and palliative treatment. The results shown in Figure 2B reduces hot flush but does not prevent nor cure hot flush.

(7) The quantity of experimentation necessary:

The instant claims read on the prevention of hot flush. As discussed above the specification fails to provide any support for preventing or curing hot flush. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that “ a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable. As demonstrated by Barton et al., desipramine only barely reduces hot flush, and Berendsen demonstrates that 5HT2 antagonist reduce hot flush. Therefore, nether drug is known to prevent nor cure hot flush. One skilled in the art would need to perform tests on normal patients for years after administering the combination drug therapy and monitor that the patients never had hot flush. The effective amount would need to be established as well.

In conclusion, the applicant is enabled for treating hot flush, but not for preventing or curing hot flush.

**2) Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hot flush with desipramine in combination with MDL-100907, does not reasonably provide enablement for treating hot flush with the derivatives of desipramine and MDL-100907. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.**

The instant claims are drawn to a method of treating hot flush in a subject comprising administering desipramine, its deravatives and or pharmaceutically acceptable salts in combination with (+)-α- (2,3-dimethoxyphenyl)-l\- [2-(4-flurophenyl)ethyl]-4-piperidinemethanol (MDL-100907), its derivatives or pharmaceutically acceptable salts. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 1 is drawn to "a method for treating hot flush in a subject, comprising the step of: administering to said subject an effective amount of desipramine, its derivatives and or pharmaceutically acceptable salts thereof in combination with an effective amount of is (+)-a- (2,3-dimethoxyphenyl)-l\- [2-(4-flurophenyl)ethyl]-4-piperidinemethanol its derivatives and or pharmaceutically acceptable salts thereof."

(2) The breadth of the claims:

Claim 1 embraces and reads of preventing and curing hot flush. The specification does not enable the prevention or the cure of hot flush.

(3) The state of the prior art:

The state of the art regarding preventing or curing hot flush is very low or do not exist. Barton et al. (Support Cancer Ther., Sep 2007, vol. 4, No. 4, pp. 219-224) teach that desipramine did not reduce hot flashes beyond the 25%-30% reduction that would be expected with placebo (see abstract, last 5 lines). Berendsen teaches that it is believed that the 5-HT2a receptor subtype may play a key role in the occurrence of hot flushes (see abstract, in particular.) In particular, Berendsen teaches that blockade of 5-HT2a receptors by treatment with the 5-HT2 receptor blocker mirtazapine reduced the frequency and intensity of hot flushes (see pages 159-160, Section 1, in particular.) Since MDL-100907 is a 5-HT2a agonist, one would expect it to be effective in reducing the frequency and intensity of hot flushes. Therefore, a 5-HT2a agonist activity is at least required to treat hot flush.

(4) The predictability or unpredictability of the art:

The predictability of all desipramine and MDL-100907 derivatives being effective in treating hot flush is relatively low, and therefore highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high as demonstrated by Barton et al.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to treating hot flush with any derivative of desipramine or MDL-100907 is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that treat hot flush with any derivative of desipramine or MDL-100907. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02. The results shown in Figure

2B reduces hot flush with the combination of desipramine and MDL-100907 but does provide any testing with a derivative of either compound.

(7) The quantity of experimentation necessary:

The instant claims read on the treating hot flush with any derivative of desipramine and MDL-100907. As discussed above the specification fails to provide any support for treating hot flush with any derivative of desipramine and MDL-100907. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable. As demonstrated by Barton et al., desipramine only barely reduces hot flush, and Berendsen demonstrates that 5HT2 antagonists reduce hot flush. Therefore, one skilled in the art would need to perform tests determine if each derivative of MDL-100907 was a 5HT2 antagonist, and if each derivative of desipramine was effective. The effective amount of each compound would also need to be established.

In conclusion, the applicant is enabled for treating hot flush with desipramine and MDL-100907, but not with a derivative of desipramine and MDL-100907.

## *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**(1) Claims 1, 14-18, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berendsen ("The Role of Serotonin in Hot Flushes", 2000, Maturitas, vol. 36, pages 155-164) in view of Stearns et al. ("A Pilot Trial Assessing the Efficacy of Paroxetine Hydrochloride (Paxil®) in Controlling Hot Flashes in Breast Cancer Survivors", Annals of Oncology, 2000, Vol. 11, pages 17-22), Janowsky et al. ("Desipramine: An Overview", The Journal of Clinical Psychiatry, 1984, Vol. 45, No. 10, Sec. 2, pages 3-7.), and Carr et al (WO 91/18602).**

Berendsen teaches that it is believed that the 5-HT2a receptor subtype may play a key role in the occurrence of hot flushes (see abstract, in particular.) In particular, Berendsen teaches that blockade of 5-HT2a receptors by treatment with the 5-HT2 receptor blocker mirtazapine reduced the frequency and intensity of hot flushes (see pages 159-160, Section 1, in particular.) Thus, Berendsen teaches treatment of vasomotor symptoms in a subject by administering a therapeutically effective amount of a 5-HT2a antagonist (i.e. mirtazapine), as recited in claim 1.

It is furthermore noted that Berendsen teaches that the mixed 5-HT and noradrenaline reuptake inhibitor venlafaxine has been shown to reduce the frequency and severity of hot flushes in women (see page 160, Section 3, in particular.) Accordingly, it is considered that Berendsen teaches treatment of vasomotor symptoms in a subject by administering a therapeutically effective amount of a norepinephrine reuptake inhibitor (noradrenaline reuptake inhibitor, i.e. venlafaxine).

Berendsen does not teach desipramine or (+)-$\alpha$-(2,3-dimethoxyphenyl)-1-[2-(4-fluorophenyl)ethyl]-4-piperidinemethanol. Berendsen also does not teach a two component method.

Stearns et al. teaches that hot flashes are accompanied by co-existing symptoms, including depression, nervousness, agitation and insomnia and inability to concentrate, which symptoms can also exacerbate the hot flashes (see page 17, left hand column, second full paragraph, in particular.) Accordingly, Stearns et al. teaches that depression is a condition that commonly co-exists with, and exacerbates, individuals suffering from hot flashes and is also commonly associated with menopause in general (see paragraph bridging pages 17-18, in particular.)

Janowsky et al. teaches that desipramine is an efficacious antidepressant that is comparable with other antidepressants such as amitriptyline, doxepin and imipramine (see page 3, left hand column, first full paragraph, in particular.) Accordingly, Janowsky et al. teaches that the specific compounds as recited in claim 4, such as desipramine, can be administered for the treatment of depression.

Carr et al. teaches a new 5HT2 antagonist that is (+)-a- (2,3-dimethoxyphenyl)-l\-[2-(4-flurophenyl)ethyl]-4-piperidinemethanol (see abstract, in particular) and that can be used for therapeutic treatment of disease states, as recited in the claim.

Although Berendsen does not teach a two component method as claimed in claim 1, Berendsen teaches two compounds, namely mirtazapine (a 5-HT2a antagonist) and venlafaxine (a mixed 5-HT2a antagonist and noradrenaline reuptake inhibitor), that have the recited activities and that are both effective for the treatment of hot flashes, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide both mirtazapine and venlafaxine type compounds (i.e. compounds with noradrenaline reuptake inhibitor and 5-HT2a antagonist activity) in effective amounts for the treatment of hot flashes, with the expectation of providing a suitable treatment for the condition. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the method of administering a 5-HT2a receptor antagonist as a first component and a norephinephrine reuptake inhibitor as a second component to treat hot flush is obvious over the teachings of Berendsen.

Regarding claims 14-15, Berendsen teaches the treatment of human females, as discussed above. Regarding claim 17, Berendsen teaches that the 5-HT2a receptor blockers can treat menopausal women (see pages 159-160, Section 1, in particular.)

Regarding claims 16 and 18, Berendsen teaches that hot flushes can occur during the perimenopausal period or after menopause (see page 156, right hand column, first full paragraph, in particular.) Accordingly, given that Berendsen teaches that the compounds can treat hot flashes, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to administer one or more of the compounds to perimenopausal or post-menopausal women experiencing hot flashes, with the expectation of achieving some treatment and/or amelioration of the hot flashes.

Regarding claims 21-22, it is considered that as the references render obvious the administration of the compounds for the treatment of the hot flash condition and co-symptoms of the condition, one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the administration of the drugs, such as by providing concurrent or simultaneous administration, according to the guidance provided by the references, to provide a treatment method with desired properties, such as desired treatment efficacy. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the specific antagonist of Carr et al. in the treatment method of Berendsen, because Berendsen teaches that compounds having 5-HT2 antagonist activity are effective in treating hot flashes, whereas Carr et al. teaches a specific 5-HT2 antagonist that can be administered for therapeutic use. Thus, one of ordinary skill in the art would have been motivated to provide the specific compound having the 5-HT2 antagonist activity in the method of Berendsen, with the expectation of success in achieving treatment of hot flashes in the patients. Accordingly, claim 5 is obvious over the teachings of Berendsen and Carr et al.

**(2) Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berendsen (Maturitas, vol. 36, pages 155-164) in view of Stearns et al. (Annals of Oncology, 2000, Vol. 11, pages 17-22), Janowsky et al. (The Journal of Clinical Psychiatry, 1984, Vol. 45, No. 10, Sec. 2, pages 3-7) and Carr et al (WO 91/18602) as applied to claims 1, 14-18, 21 and 22 above, and further in view of Quella et al. ("Pilot Evaluation of Venlafaxine for the treatment of Hot Flashes in**

**Men Undergoing Androgen Ablation Therapy for Prostate Cancer", 1999, Journal of Urology, vol. 162, pages 98-102.)**

The teachings of Berendsen, Stearns et al., Janowsky et al. and Carr et al. are as in claims 1, 14-18, 21 and 22 above. Particularly a method of treatment for patients suffering from hot flashes with the compounds as recited in the claims.

Berendsen, Stearns et al., Janowsky et al. and Carr et al. does not specifically teach treatment of male patients (claim 19), or male patients that are naturally, chemically or surgically andropausal, as recited in claim 20.

Quella et al. teaches that men undergoing androgen ablation therapy experience hot flashes (see abstract, in particular.) Quella et al. teaches treatment of hot flashes in men undergoing androgen deprivation therapy for prostate cancer (see page 98, first full paragraph), and thus teaches the treatment of male patients that are chemically or surgically andropausal, as recited in the claims.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to treat men to alleviate hot flashes, such as andropausal men, because Quella et al. teaches that such men experience hot flashes, whereas Berendsen teaches a method of treating such hot flashes. Thus, one of ordinary skill in the art would have been motivated to treat the men having hot flashes with the method of Berendsen, with the expectation of success in treating the hot flashes.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that assuming *in arguendo* that the 5HT2 antagonist MDL-100907 could be predicted by one of skill in the art to have anti-hot flush efficacy, one of ordinary skill in the art could not have predicted that the combination of desipramine and MDL-100907 would have more than additive (synergistic) effects on the reduction of hot flush as demonstrated in Figure 2B of the specification.

The Examiner disagrees because the additive effects presented in Figure 2B are not commensurate in scope with the claims. The results demonstrated in Figure 2B are with the specific compounds desipramine and MDL-100907 with specific amounts, whereas the current claims allow derivatives of both compounds and the amounts are only restricted by an effective amount. It is noted that evidence of unexpected results is required to be reasonably commensurate in scope with the claimed invention. See, e.g., In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983).

***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617